

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 2026

### Comparison the effect of breastfeeding and oral glucose (10%) on the severity of pain and physiologic characteristics due to venous sampling in infants who Hospitalized in neonatal intensive care unit

#### Protocol summary

Registration timing: **registered\_while\_recruiting**

##### Study aim

Comparison the effect of breastfeeding and oral glucose (10%) on the severity of pain and physiologic characteristics due to venous sampling in infants who Hospitalized in neonatal intensive care unit.

##### Design

Clinical trial with control group, with parallel groups, without blinding

##### Settings and conduct

The researcher will refer to Seyedoshohada hospital and then the sample according to inclusion criteria will be divided to three homogeneous groups. Intervention will perform once for members of each group . Physiologic responses will be documented 10 min before intervention, during intervention and 10 min after intervention and neonatal pain will be assessed during intervention.

##### Participants/Inclusion and exclusion criteria

Infants with gestational age more than 30 weeks, Infants without congenital anomalies

##### Intervention groups

Intervention group 1: they will be embraced the mother and during blood sampling will be eaten breast milk.  
Intervention group 2: they will be embraced the mother and during blood sampling will be eaten oral 10% glucose. Control group: they will be embraced the mother without any intervention during blood sampling.

##### Main outcome variables

Physiological responses, Pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190105042245N1**

Registration date: **2019-02-24, 1397/12/05**

Last update: **2019-02-24, 1397/12/05**

Update count: **0**

##### Registration date

2019-02-24, 1397/12/05

##### Registrant information

###### Name

Mojgan Saeidinejad

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 34 3247 2508

###### Email address

m.saednejad@kmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-02-20, 1397/12/01

##### Expected recruitment end date

2019-08-22, 1398/05/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison the effect of breastfeeding and oral glucose (10%) on the severity of pain and physiologic characteristics due to venous sampling in infants who Hospitalized in neonatal intensive care unit

##### Public title

Comparison the effect of breastfeeding and oral glucose (10%) on the severity of pain and physiologic characteristics due to venous sampling in infants

#### **Purpose**

Education/Guidance

#### **Inclusion/Exclusion criteria**

##### **Inclusion criteria:**

Gestational age more than 30 weeks  
Lack of congenital anomalies  
Lack of mechanical ventilation

##### **Exclusion criteria:**

Having nutritional problems  
receive sedatives three hours before intervention

#### **Age**

From **1 day** old to **28 days** old

#### **Gender**

Both

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **135**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

The sample will be selected from preterm infants according to inclusion criteria. Thus, blocks will be created based on personal information and inside of each block will be divided to three equal parts. Each part is assigned to intervention group 1, intervention group 2 and control group, respectively.

#### **Blinding (investigator's opinion)**

Not blinded

#### **Blinding description**

##### **Placebo**

Not used

##### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

##### **Ethics committee**

###### **Name of ethics committee**

Ethics committee of Kerman University of Medical Sciences

###### **Street address**

Campus of Kerman medical science university, Haft-Bagh Highway

###### **City**

Kerman

###### **Province**

Kerman

###### **Postal code**

7616913555

##### **Approval date**

2018-12-15, 1397/09/24

#### **Ethics committee reference number**

IR.KMU.REC.1397.343

### **Health conditions studied**

#### **1**

##### **Description of health condition studied**

Physiological responses

##### **ICD-10 code**

##### **ICD-10 code description**

#### **2**

##### **Description of health condition studied**

pain

##### **ICD-10 code**

G89.18

##### **ICD-10 code description**

Other acute postprocedural pain

### **Primary outcomes**

#### **1**

##### **Description**

Arterial oxygen saturation

##### **Timepoint**

Before, during and after intervention

##### **Method of measurement**

Pulseoximetry

#### **2**

##### **Description**

Pulse rate

##### **Timepoint**

Before, during and after intervention

##### **Method of measurement**

Pulseoximetry

#### **3**

##### **Description**

Pain

##### **Timepoint**

During intervention

##### **Method of measurement**

NIPS Questionnaire

### **Secondary outcomes**

empty

### **Intervention groups**

#### **1**

##### **Description**

Intervention group 1: this group will be embraced the mother and they will be eaten breast milk. Physiological

responses will be documented 10 min before intervention, during intervention and 10 min after intervention. Neonatal pain will be checked according to questionnaire.

**Category**

Other

**2**

**Description**

Intervention group 2: this group will be embraced the mother and they will be eaten oral 10% glucose. Physiological responses will be documented 10 min before intervention, during intervention and 10 min after intervention. Neonatal pain will be checked according to questionnaire.

**Category**

Other

**3**

**Description**

Control group: this group will be embraced the mother and will not perform any intervention. Physiological responses will be documented 10 min before intervention, during intervention and 10 min after intervention. Neonatal pain will be checked according to questionnaire.

**Category**

Other

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Seyedoshohada Hospital

**Full name of responsible person**

Mojgan Saeidinejad

**Street address**

Seyedoshohada hospital, Esteghlal st.,

**City**

Kerman

**Province**

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**Postal code**

7617755178

**Phone**

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**Email**

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**Web page address**

http://teb.police.ir/hospitals

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Reza Dehnaviyeh

**Street address**

Kerman medical sciences university, Haft bagh highway

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**Phone**

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**Email**

rdehnavi@gmail.com

**Web page address**

http://kmu.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Kerman University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

Academic

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Mojgan Saeidinejad

**Position**

Nursing MSc student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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No 8., Esteghlal st.,

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Mojgan Saeidinejad

**Position**

Nursing MSc student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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## Person responsible for updating data

**Contact**

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Kerman University of Medical Sciences

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**Latest degree**

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**Other areas of specialty/work**

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+98 34 3247 2508

**Email**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

Relied on secrecy

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available